Home Care Provider Setup Instructions

Always use these instructions along with the User Manual when assembling or adjusting this equipment. For clinical systems, refer to the setup guide entitled Respironics Products in the Sleep Lab (part #1009751) for equipment setup assistance.

REMstar® | plus

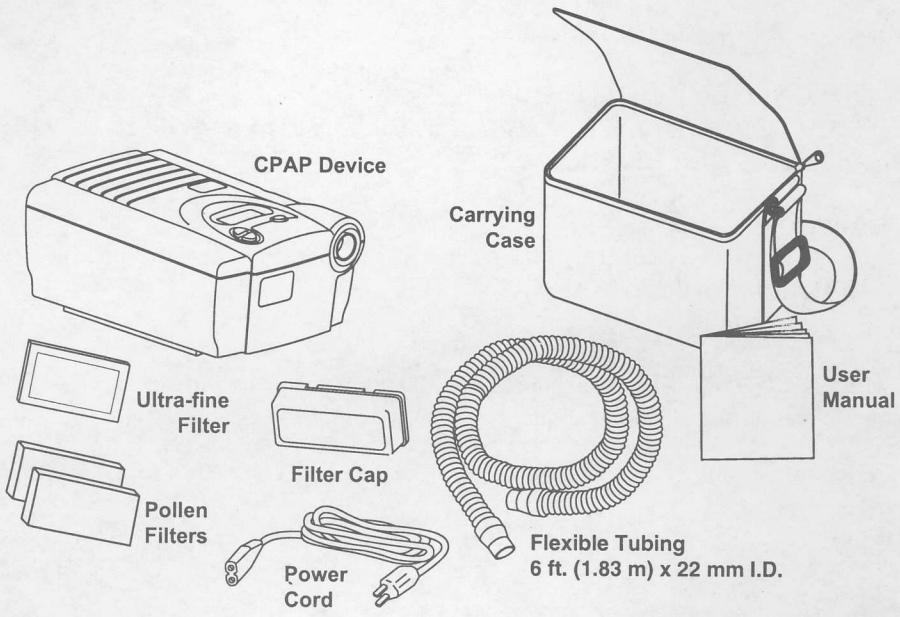
CPAP System

This CPAP System is intended only for the treatment of adult Obstructive Sleep Apnea.

RESPIRONICS®
www.respironics.com

IMPORTANT! ***For devices with serial numbers greater than 2,000,000, the display screen has been updated and an 8-pin communications connector has been added.***

System Contents



Symbols

Display Screen

- Elevation
- Ramp Start Pressure
- Humidifier Setting
- Hours of Use
- >4 — Number of nights with more than 4 hours usage
- Therapy Setup Menu
- Settings are being erased
- Button Lights

Control Buttons

- Pressure Start / Stop
- Ramp
- Humidifier On / Off

Device Label

- Attention, consult accompanying documents
- ~ AC Power
- DC Power
- Type BF Applied Part
- Class II (Double Insulated)
- IPX0 — Ordinary Equipment
- CE 0123 — European CE Declaration of Conformity
- VDE — Notified Body Approval for Standards Compliance
- C SP® US — Canadian/US Certification
- Electrostatic Discharge (ESD) Susceptibility

Specifications

AC Power Consumption: 100 - 240 VAC, 50/60 Hz, 1.0 A max.

DC Power Consumption: 12 VDC, 3.0 A max.

Pressure Increments: 4.0 to 20.0 cm H_2O (in 1.0 cm H_2O increments)

Degree of Protection against Ingress of Water: IPX0 Ordinary Equipment

Mode of Operation: Continuous

Type of Protection against Electric Shock: Class II Equipment

Degree of Protection against Electric Shock: Type BF Applied Part

Pressure Display Accuracy: +/- (0.15 + 4% of actual reading)

Pressure Stability: 4.0 to 20.0 cm H_2O (±1.0 cm H_2O)
Measured in accordance with EN 17510 @ 7, 13, & 20 cm H_2O @ 500 ml with BPM set to 10, 15, & 20 BPM @ 23° C (±2° C), 50a% RH (±5%), and an atmospheric pressure of 101.54 kPascals.

Sound Pressure Level: <30 dB(A)
Measured in accordance with EN 17510 @ 10 cm H_2O at the patient circuit. This measurement applies to the REMstar Plus with or without the optional REMstar Heated Humidifier.

Maximum Flow: 35 LPM
Measured in accordance with EN 17510 @ 7, 13, & 20 cm H_2O @ 500 ml with BPM set to 10, 15, & 20 BPM @ 23° C (±2° C), 50% RH (±5%), and an atmospheric pressure of 101.54 kPascals.

CAUTION!
Indicates the possibility of damage to the device.

- US federal law restricts this device to sale by or on the order of a physician.

WARNING!
Indicates the possibility for injury to the user or operator.

- *This device is intended for adult use only.*
- *This device is not intended for life support.*
- *CPAP devices have the potential to induce rebreathing of exhaled air. To reduce this potential, observe the following:*
  - *Use Respironics circuit accessories.*
  - *Do not wear the mask and headgear for more than a few minutes while the unit is not operating.*
  - *Do not block or try to seal the vent holes in the exhalation port.*

  As with most CPAP devices, at low CPAP pressures, some exhaled gas (CO_2) may remain in the mask and be rebreathed.
- *Do not use this device if the room temperature is warmer than 95° F (35° C). If this device is used at room temperatures warmer than 95° F (35° C), the temperature of the airflow may exceed 106° F (41° C). This could cause irritation to the patient's airway.*
- *This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.*
- *If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, or if the enclosure is broken, discontinue use. Contact Respironics Customer Service Department and replace any damaged parts before continuing use.*
- *To avoid electrical shock, disconnect the power cord before cleaning. DO NOT immerse the REMstar Plus in any fluids.*
- *Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used. Precautionary procedures include methods to prevent build-up of electrostatic discharge (e.g., air conditioning, humidification, conductive floor coverings, and non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and bonding oneself by means of a wrist strap to the equipment or system or to earth.*

Contraindications

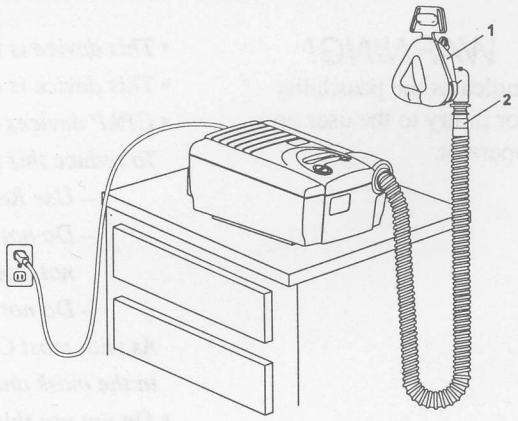
When assessing the relative risks and benefits of using this equipment, the clinician should understand that this device can deliver pressures up to 20 cm H_2O. In the event of certain fault conditions, a maximum pressure of 30 cm H_2O is possible. Studies have shown that the following pre-existing conditions may contraindicate the use of CPAP therapy for some patients:

- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Pneumothorax
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus. (Chest 1989; 96:1425-1426)

The use of CPAP therapy may be temporarily contraindicated if a patient exhibits signs of a sinus or middle ear infection. Not for use with patients whose upper airways are bypassed. Should your patient have any of these conditions, a physician will determine if CPAP therapy is appropriate.

Accessories

WARNING! *Do not connect any equipment to the REMstar Plus unless recommended by Respironics or the doctor. Verify that an exhalation port is present to exhaust CO_2 from the circuit. If circuit accessories, other than those recommended by Respironics, are connected to the REMstar Plus, pressures must be verified. Use of these accessories may alter the pressure received, reducing the effectiveness of treatment.*



Respironics Accessories

When using accessories, always follow the instructions enclosed with the accessories.

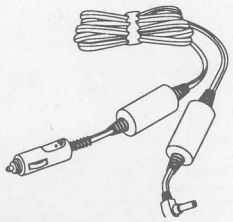
Recommended Patient Circuit

1. **Respironics nasal mask with integrated exhalation port** (or Respironics mask with separate exhalation port such as the Whisper Swivel® II)
2. **Respironics 6 ft. (1.83 m) x 22 mm I.D. flexible tubing**
3. **Respironics headgear** (not shown)

WARNING! ***If this device is used for multiple persons (e.g., rental devices) a low-resistance, main flow bacteria filter should be installed in-line between the device and the circuit tubing. Pressures must be verified when alternate or optional accessories are in place.***

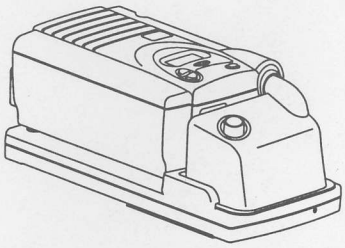
DC Power

The Respironics DC Power Cord can be used to operate this device in a stationary recreational vehicle, boat, or motor home. The **Respironics DC Battery Adapter Cable** (when used with the Respironics DC Power Cord) enables the device to be operated from a 12 VDC free-standing battery.



Humidifiers

The Respironics REMstar Heated Humidifier and Pass-over Humidifier are available for use with this device. The humidifiers may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow. **When using other humidifiers, verify that the delivered pressure is correct and that proper therapy is being delivered. DC power cannot be used to operate the heated humidifier.**



Oxygen

Oxygen may be added at the mask connection. Please note the warnings listed below when using oxygen with this device.

WARNING! ***The oxygen supply must comply with the local regulations for medical oxygen.***

WARNING! ***A Respironics Pressure Valve (Part number 302418) must be placed in-line with the patient circuit.***

WARNING! ***Turn this device on before turning the oxygen on. Turn the oxygen off before turning this device off. This will prevent oxygen accumulation in the device.***

WARNING! ***Oxygen accelerates fires. Keep this device and the oxygen container away from heat, open flames, any oily substance, or other sources of ignition. DO NOT smoke in the area near this device or the oxygen container.***

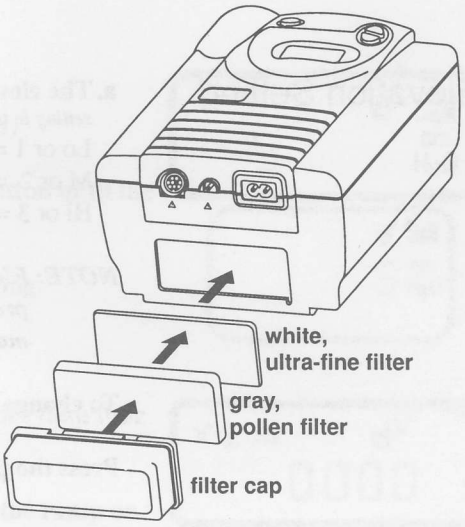
WARNING! ***When administering fixed-flow supplemental oxygen, the O_2 concentration may not be constant. The inspired oxygen concentration will vary depending on the CPAP settings, patient breathing pattern, and the leak rate. Substantial leaks around the mask may reduce the inspired oxygen concentration to less than the expected concentrations. Appropriate patient monitoring should be implemented.***

Filters

Install the filters.

CAUTION!

The pollen filter must be in place at all times when the REMstar Plus is operating. The white ultra-fine filter is optional and can be used in addition to the pollen filter. The ultra-fine filter is recommended for people who are sensitive to tobacco smoke or other small particles.



1. If you are using the ultra-fine filter, place one of the pollen filters over the ultra-fine filter.

2. Insert the filter(s) into the filter area on the back of the REMstar Plus. An extra filter is included for the patient's convenience.

3. Attach the filter cap. Position the cap so that the small opening on the cap is facing down. Insert the cap's tabs into the filter area opening.

CAUTION!

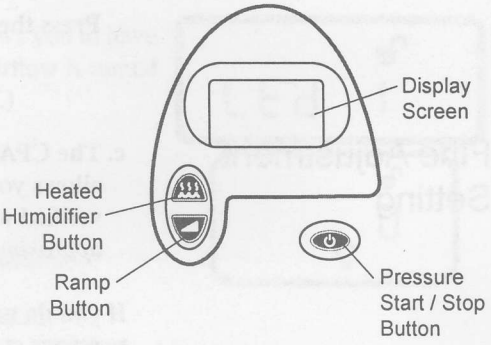
If this device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature before beginning the following setup procedures.

Control Panel

Display Screen: All device settings will appear here.

Pressure Start/Stop Button: Use this button to turn start or stop the airflow. DO NOT start the airflow until the circuit tubing is connected.

Humidifier Button: Use this button when the optional REMstar Heated Humidifier has been prescribed. This button will turn the humidifier on/off and control the heat setting. Follow the instructions included with the humidifier.



Ramp Button: Use this button to start the ramp cycle (which lowers the airflow pressure).

IMPORTANT!

When the device is in the Therapy Setup Menu, the humidifier and ramp buttons operate as up and down keys to change the settings. The pressure start/stop button will take you to the next screen.

IMPORTANT!

For devices with serial numbers of 2,000,000 and greater, the display screen has been updated and an 8-pin communications connector has been added. Both display screens are shown below.

Therapy Setup Menu

1. Plug the pronged end of the power cord into an electrical outlet. To enter the Therapy Setup Menu, hold the ramp and pressure on/off buttons down while plugging the power cord into the device. The airflow will automatically start, and the display screen will show the current elevation setting and the unlock symbol.

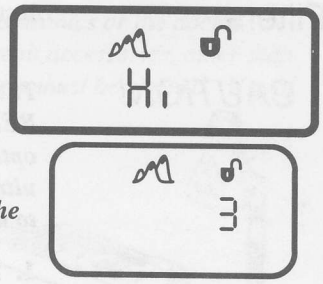
IMPORTANT!

Prescribed therapy settings can be set only using the Therapy Setup Menu. To prevent patients from tampering with the settings, do not reveal the directions to access the Therapy Setup Menu.

Elevation Setting

a. The elevation setting will appear. *The patient also has access to this setting in the Patient Setup Menu.*

Lo or 1 = less than 2,500 ft. (< 762 m)
M or 2 = 2,500 to 5,000 ft. (762 m to 1524 m)
Hi or 3 = 5,001 to 7,500 ft. (1525 m to 2286 m)



NOTE: Elevations of 7,500 ft. (2,286 m) may affect the accuracy of the pressure. Verify the pressure settings with a water column manometer.

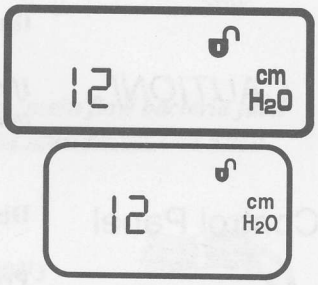
To change the setting, press the ramp or humidifier button until the correct setting appears.

Press the pressure start/stop button to go to the next setting.

Pressure Setting

b. The CPAP pressure setting will appear.
Range: 4 to 20 cm H_2O (in 1 cm H_2O increments)
To change the setting, press the ramp or humidifier button until the correct pressure appears.

Press the pressure start/stop button to go to the next setting.

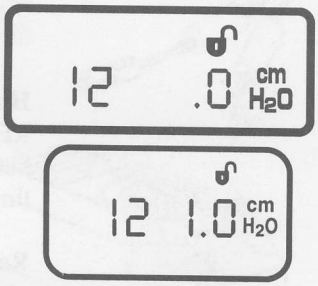


Fine Adjustment Setting

c. The CPAP fine adjustment setting will appear. This setting allows you to calibrate the device so that the pressure setting can be verified with a manometer. *Range: ≥ -1.5 to 1.5 cm H_2O (in approximately 0.1 cm H_2O increments)*

If you <u>do not</u> want to calibrate the device, press and release the pressure start/stop button to go to the next setting.

If you <u>do</u> want to calibrate the device, follow the directions below:



1. Connect the patient circuit to the REMstar Plus. Make sure there is an exhalation leak in the circuit.
2. Zero the manometer, and connect the manometer at the patient mask. Make sure the pressure has stabilized for at least 60 seconds.
3. If the pressure setting is not the same as the manometer reading, press and release the ramp or humidifier button to change the setting.

Press the pressure start/stop button to go to the next setting.

Ramp Time Setting

d. The ramp time will appear.
Range: 0 to 45 minutes (in 5 minute increments) ***The patient also has access to this setting in the Patient Setup Menu.***

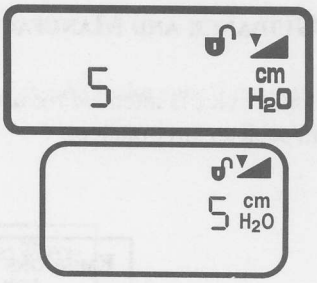
To change the setting, press the ramp or humidifier button.

Press the pressure start/stop button to go to the next setting.

NOTE: If the ramp time is set to "0" minutes, or if the CPAP pressure setting is 4 cm H_20, the following ramp setting will not be displayed. Go to Step f.

Ramp Starting Pressure Setting

e. The ramp starting pressure will appear.
Range: 4 to Prescription Setting (in 1 cm H_2O increments)

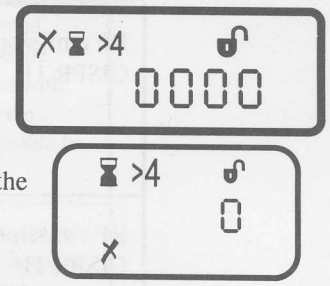


To change the setting, press the ramp or humidifier button until the correct pressure appears.

Press the pressure start/stop button to go to the next setting.

>4 Setting

f. The number of nights this device has been used for more than four consecutive hours (>4) will appear.

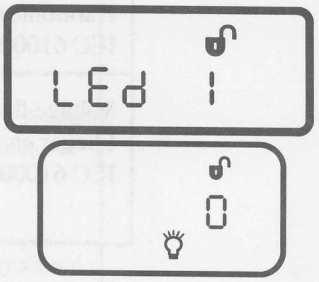


To erase the total and go back to zero, press <u>and hold</u> the ramp or humidifier button. An "X" will appear in the lower left corner and the total will change to "0000." (Pressing the button again will restore the original count.)

Press the pressure start/stop button to go to the next setting.

Button Lights

g. The button lights setting will appear. This setting allows you to have the lights behind the buttons turned on or off while the airflow is turned on. (The lights will always be on when the airflow is off.)
The patient also has access to this setting in the Patient Setup Menu.



1 = on 0 = off

To change the setting, press the ramp or humidifier button.

Exit Settings

h. The settings are complete. To repeat the settings, press the pressure start/stop button.

To exit the Therapy Setup Menu, hold the pressure start/stop button down and press the ramp button one time. The airflow will turn off.

2. Final Steps

a. Follow the instructions in the User Manual to install the filter.

b. Fill out the information form in the front of the User Manual. Review the User Manual with the patient.

Service

The REMstar Plus System does not require routine servicing. If the REMstar Plus begins to mal function, refer to the "Troubleshooting" section of the User Manual or contact Respironics, Inc. Repairs and adjustments must be performed only by trained personnel fully acquainted with this equipment. Service performed by unqualified personnel or installation of unauthorized parts could cause personal injury, invalidate the warranty, or result in costly damage.

Disposal

When necessary, dispose of the REMstar Plus and accessories in accordance with local regulations.

If you need product assistance, call

Respironics Customer Service Department
1-800-345-6443 (within he U.S. and Canada) or 1-724-387-4000

EMC Information

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

EMC Information

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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